DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 12, 2014

Harbor MedTech Incorporated
Mr. Jerry Mezger
Chief Executive Officer
4 Jenner, Suite 190
Irvine, California 92618

Re: K140367
Trade/Device Name: Architect Px Extracellular Collagen Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: August 14, 2014
Received: August 18, 2014

Dear Mr. Mezger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140367

Device Name
Architect Px Extracellular Collagen Matrix

Indications for Use *(Describe)*
The Harbor MedTech Architect™ Px Extracellular Collagen Matrix is indicated for the local management of moderately to heavy exuding wounds, including:

- Partial and full thickness wounds,
- Draining wounds,
- Pressure sores/ulcers,
- Venous ulcers,
- Chronic vascular ulcers,
- Diabetic ulcers,
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears),
- Surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced surgical incisions)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Harbor MedTech, Inc.
Architect™ Px Extracellular Collagen Matrix

ADMINISTRATIVE INFORMATION:

Date of Preparation: September 3, 2014

Manufacturer Name: Harbor MedTech, Inc.
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Additional Correspondent: Carol White, RA Consultant
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Architect™ Px Extracellular Collagen Matrix
Common Name:	Dressing, Wound, Collagen
Classification Regulation:	Unclassified
Product Code:	KGN
Device Class:	Unclassified
Review Panel:	General & Plastic Surgery

INTENDED USE
The Harbor MedTech Architect™ Px Extracellular Collagen Matrix is indicated for the local management of moderately to heavy exuding wounds, including:

- Partial and full thickness wounds,
- Draining wounds,
- Pressure sores/ulcers,
- Venous ulcers,
- Chronic vascular ulcers,
- Diabetic ulcers,
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears),
- Surgical wounds (e.g., donor sites/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced surgical incisions)

DEVICE DESCRIPTION

The Harbor MedTech Architect™ Px Extracellular Collagen Matrix (ECM) is a decellularized equine pericardial device The Architect™ Px ECM is provided sterile for single use only. The device must be rehydrated and rinsed prior to use following the procedure described in the Instructions for Use.

The Architect™ Px ECM is available in multiple sizes. The Architect™ Px ECM is available as a standard dressing and in a fenestrated model with pre-cut slits in the collagen matrix. A table of model numbers and sizes is provided below:

Model Number	Dimensions	Description
HMT-004Px	2 cm x 2 cm	Standard
HMT-009Px	3 cm x 3 cm	Standard
HMT-025Px	5 cm x 5 cm	Standard
HMT-036Px	6 cm x 6 cm	Standard
HMT-100Px	10 cm x 10 cm	Standard
HMT-150Px	10 cm x 15 cm	Standard
HMT-009F-Px	3 cm x 3 cm	Fenestrated
HMT-025F-Px	5 cm x 5 cm	Fenestrated
HMT-036F-Px	6 cm x 6 cm	Fenestrated
HMT-100F-Px	10 cm x 10 cm	Fenestrated
HMT-150F-Px	10 cm x 15 cm	Fenestrated

Due to the natural variability of extracellular collagen matrices, lot to lot variations may be seen in the handling characteristics of the finished device. The user is instructed to use their professional clinical judgment in selecting the appropriate device for the application of the product.

EQUIVALENCE TO MARKETED PRODUCT

Harbor MedTech, Inc., demonstrated that, for purposes of FDA's regulation of medical devices, the Architect™ Px Extracellular Collagen Matrix (ECM) is substantially equivalent in indications, materials, manufacturing and design principles to the predicate device which has been determined by FDA to be substantially equivalent to preamendment devices.

The Architect™ Px Extracellular Collagen Matrix has the following similarities to the predicate devices:

- has the same intended use
- uses the same operating principle
- incorporates the same basic design
- incorporates the same materials and manufacturing processes
- uses the same species of animal tissue

The Architect™ Px Extracellular Collagen Matrix differs from the predicate device in the concentration of the BDDGE solution used in the manufacturing process. The concentration of BDDGE used in the proposed device is lower than that of the predicate device.

The Harbor MedTech Architect™ Px ECM is, in our opinion, substantially equivalent to the Harbor MedTech Architect™ ECM K122502.

PERFORMANCE TESTING

A number of verification and validation studies were conducted to assess the physical attributes of the collagen biomaterial and manufacturing processing. Results of this testing confirmed that the minor changes to the manufacturing process yielded a device that conforms to the performance specifications established for the Architect™ ECM cleared under premarket 510(k) notification K122502. Verification and validation studies included Pronase digestion, differential scanning calorimetry (DSC), tissue flexibility and conformity, tensile testing, suture pull-out and staple pull-out testing. Comparative testing was performed with the predicate device: Architect™ Extracellular Collagen Matrix produced by Harbor MedTech, Inc.

Extensive biocompatibility testing and viral inactivation testing was completed and found to be acceptable. These studies were not repeated since the materials, processing, packaging and sterilization have not changed. The decreased concentration of BDDGE fixative used in the new process did not warrant a repeat of these studies.

Results of the tensile, suture pull-out, staple pull-out and flexibility testing show that the Architect™ Px ECM tissue has the mechanical strength and integrity to perform as intended.

Based on the results of the performance bench testing validations and comparison to the predicate device, Harbor MedTech has demonstrated that the Architect™ Px Extracellular Collagen Matrix is equivalent to the predicate device in terms of performance characteristics and will perform as intended for the application of the product.